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10/542,997	07/21/2005	Kazuhiro Ohkouchi	084437-0173	7856

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,997	OHKOUCHI ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *2,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/05 and 03/02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS's filed on 03/02/05 and 10/13/06 is acknowledged. Applicant's Response filed on 08/12/08 is also acknowledged. Claims 1-13 are pending.

Response to Remarks

Applicant's election without traverse of Group I, claims 1, and 3-11, in the reply filed on 08/12/08 is acknowledged. Claims 2, 12 and 13 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The remaining claims 1 and 3-11 are presented and represent all claims under consideration. Claims 1 and 3-11 will be examined and are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "A production method of a coated preparation" is unclear because it is not immediately discernible whether the claim is drawn to a production method that uses a coated preparation or manufactures it.

The recitation "coating with an aqueous dispersion of..." is vague and indefinite because it is not clear exactly what part of the preparation is being coated (i.e. individual particles or the tablet as a whole being coated).

Further, the recitation “low viscosity” is vague and indefinite because there are no "metes and bounds” to the instant claim 1. The claim is being interpreted with the broadest reasonable interpretation, as evidenced by the prior art EP 0616841 low viscosity binders include hydroxypropylcellulose, hydroxypropylmethylcellulose, sodium carboxymethylcellulose and polyvinylpyrrolidone (claim 6).

Claim 4 contains the trademark/trade name SL or SSL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydroxypropyl cellulose and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/82875 ('875) as cited by Applicant.

The instant claims are drawn to a production method of a coated preparation, which comprises coating with an aqueous dispersion of pioglitazone hydrochloride comprising a coating material having a low viscosity.

- '875 teaches in claim 8, a method for producing a combined formulation of pioglitazone HCl and metformin comprising a) forming a core of the metformin and b) depositing a layer of pioglitazone hydrochloride on at least a portion of the surface of said core (pg. 2, lines 20-30; pg. 3, lines 3-6). '875 teaches that the shell layer comprising the pioglitazone HCl is formed via solvent removal process (pg. 7, line 31-pg. 8, line 2) and that cellulosic polymers and polyvinyl alcohol are

taught as a biodegradable material further included in the coating of the dosage form (pg. 7, lines 21-27) (according to the limitations of claim 1 and 5-7).

- '875 defines "metformin" to mean the base compound as well as its pharmaceutically acceptable salts, including metformin hydrochloride (pg. 1, lines 27-29) (according to the limitation of claim 8).
- '875 teaches the same method of coating a dosage form with the same composition as instant claimed and it is therefore assumed in the absence of evidence otherwise to have the same dissolution improvement (as required by the limitation of claim 11).

Claims 1, 5-8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0106660 ('660) (which has priority to 09/20/2002) as cited by Applicant.

The instant claims are drawn to a production method of a coated preparation, which comprises coating with an aqueous dispersion of pioglitazone hydrochloride comprising a coating material having a low viscosity.

- '660 teaches a combined formulation of pioglitazone HCl and metformin comprising a) forming a core of the metformin HCl and b) depositing coating layer of pioglitazone hydrochloride and polymer in water on the surface of said core (abstract, [0016], Examples 1-2) (according to the limitations of claims 1 and 5-8).

- '660 teaches that the binder (hydroxypropylmethyl cellulose or hydroxypropylcellulose) is included in the composition in an amount of 1-15% by weight of the total dosage form ([0042] table) (meeting the limitations of claim 3).
- '660 teaches that the coating is formed via spraying a suspension of comprising the pioglitazone HCl and hydroxypropylmethylcellulose or hydroxypropylcellulose in purified water ([0035, 0023], [0042] table; and Examples 1-2).
- '660 teaches a method of coating a dosage form with the same composition as instant claimed and and it is therefore assumed in the absence of evidence otherwise to have the same dissolution improvement (as required by the limitation of claim 11).

Claims 1, 5 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0060488 ('488).

The instant claims are drawn to a production method of a coated preparation, which comprises coating with an aqueous dispersion of pioglitazone hydrochloride comprising a coating material having a low viscosity.

- Example 1 teaches pioglitazone HCl combined with an aqueous solution with hydoxypropylcellulose (according to the limitation of claim 1). '488 teaches that oral preparation for the actives can be prepared by mixing separately and that such binders like hydroxypropylmethylcellulose or hydroxypropylcellulose can be used in the core or in the coating [0154, 0157-0158].

- '488 teaches a combination of an insulin sensitizer preferably pioglitazone HCl with a HMG-CoA reductase inhibitor like a statin compound such as pravastatin, simvastatin, atorvastatin, etc [0009, 0023, 0025-0026, 0123, 0139, 0145-0148] (according to claims 5 and 9-10). '488 teaches teaches a method of coating a dosage form with the same composition as instant claimed and and it is therefore assumed in the absence of evidence otherwise to have the same dissolution improvement (as required by the limitation of claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. US 2003/0060488 ('488) in view of WO 01/82875 ('875) or US 2004/0106660 ('660).

The instant claims are drawn to a production method of a coated preparation, which comprises coating with an aqueous dispersion of pioglitazone hydrochloride comprising a coating material having a low viscosity.

- '488 is taught above and teaches a combination of an insulin sensitizer preferably pioglitazone HCl with a HMG-CoA reductase inhibitor like a statin compound such as pravastatin, simvastatin, atorvastatin, etc [0009, 0023, 0025-0026, 0123, 0139, 0145-0148] (according to claims 1, 5 and 9-10). '488 teaches that such a combination is desirable since a lower dose of the pharmaceutical agents can be used for therapeutic results which decreases the amount of unpreferable action of these actives and enhanced preferred activity [0173-0174] (according to the limitations of claims 1 and 11).

'488 does not teach a coating containing pioglitazone HCl over a core containing an active, but does teach that a coating comprising water soluble polymers such hydroxypropylmethylcellulose or hydroxypropylcellulose, etc can be included [0158].

- '875 teaches that the shell layer comprising the pioglitazone HCl is formed via solvent removal process (pg. 7, line 31-pg. 8, line 2) and that cellulosic polymers and polyvinyl alcohol are taught as a biodegradable material further included in the coating of the dosage form (pg. 7, lines 21-27) (according to the limitations of claim 1 and 5-7). '875 teaches that additional actives (a third pharmaceutical) can be added to the core (pg. 3, lines 10-14 or pg. 6, lines 9-11).
- '660 is taught above and teaches a coating is formed via spraying a suspension of comprising the pioglitazone HCl and hydroxypropylmethylcellulose or hydroxypropylcellulose in purified water ([0035, 0023], [0042] table; and

Examples 1-2) (according to the limitations of claim 1, 3-8 and 11). '660 teaches that a second active drug can be incorporated into the dosage form with the first active [0034].

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

"[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to shift the position of the pioglitazone hydrochloride within the composition from being generally combined with, as practiced by '488, to being dispersed within the coating that surrounds the active core, as practiced by '875 or '660 with a reasonable expectation of manufacturing a coated dosage form capable of

delivering dual active ingredients to patients. Such would have been obvious in the absence of evidence to the contrary because '875 or '660 teach that the creation of a formulation where multiple medicaments create a synergistic effect and further '488 teaches that an enhanced effect is observed for the combination of pioglitazone HCl with a HMG-CoA reductase inhibitor [0173-0174]. It is also taught that the '488 actives can be formulated separately and a '488 coated core formulation is known, while '875 or '660 are simply relied upon to teach the technique of placing the second active (or pioglitazone HCl) into the coating. Thus a combination of a known product (i.e. pioglitazone HCl with a HMG-CoA reductase inhibitor) with synergistic effect is known in the art and the known technique of spray drying a coating comprising pioglitazone HCl into a dosage form is also known and such a rearrangement of the second active from within the core to the outer coating is not outside the purview of the skilled artisan.

Claims 1, 3-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/82875 ('875) or US 2004/0106660 ('660) in view of 2004/0092480 (480).

The instant claims are drawn to a production method of a coated preparation, which comprises coating with an aqueous dispersion of pioglitazone hydrochloride comprising a coating material having a low viscosity.

- '875 is taught above and teaches that the shell layer comprising the pioglitazone HCl is formed via solvent removal process (pg. 7, line 31-pg. 8, line 2) and that cellulosic polymers and polyvinyl alcohol are taught as a biodegradable material

further included in the coating of the dosage form (pg. 7, lines 21-27) (according to the limitations of claim 1 and 5-7).

- '660 is taught above and teaches a coating is formed via spraying a suspension of comprising the pioglitazone HCl and hydroxypropylmethylcellulose or hydroxypropylcellulose in purified water ([0035, 0023], [0042] table; and Examples 1-2) (according to the limitations of claim 1, 3-8 and 11).

'660 or '875 do not specific the type of HPC used in the as a binder but teach generically HPC.

- '480 teaches known binders in a pharmaceutical compositions include HPC of various molecular weights and that HPC whose 2% weight aqueous solution has a viscosity of especially 3-10 cps is preferred including HPC-SL (registered trademark) [0011] (meeting the limitations of claims 3-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one HPC into the pharmaceutical formulations of '875 or '660 with the specific HPC disclosed by '480 . A skilled artisan would know how to substitute one known HPC binder of '875 or '660 for the specific HPC binder of '480 as such a substitution is not outside the purview of the skilled artisan.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-

6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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